Commentary

Progressing the Certification of the Medical Science Workforce

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Abstract

The Australian Commonwealth Government has funded a project to investigate options for a sustainable certification scheme for medical laboratory scientists (MLSs). This has been a sought-after goal for the profession in Australia for many years. Certification is not registration as certification may not be mandatory and does not have the legal teeth of the more formal process. Models of overseas registration schemes are discussed and the key features exposed. The definition of an MLS is needed as certification will provide protection of the title. What are the basic requirements for certification and recertification, what could the process be, the likely cost and period of validity? An essential component of the certification process would be some form of continuing professional development, but it is suggested that there should be a broader requirement for competence assessment for recertification. How this process could occur and be linked to the competency-based standards endorsed by the Pathology Associations Council is canvassed. The connection between certification and course accreditation should also be considered if courses are to provide work-ready MLSs in sufficient numbers to ensure the workforce can provide the necessary skills for the protection of the public.

Introduction

In late 2017, the Australian Department of Health, via the Quality Use of Pathology Program, facilitated by Human Capital Alliance (HCA), funded a project designed to improve the efficiency and objectivity of the Australian pathology accreditation arrangements by providing a relevant mechanism for assuring competence of the scientific pathology laboratory workforce.[1] This was to be achieved by developing and implementing a fair, transparent and effective national model of certification of pathology laboratory scientist competence to provide a more objective indication of readiness for different levels of laboratory practice. The project was administered by the Australian Institute of Medical Scientists (AIMS) and overseen by a project steering committee consisting of AIMS, the Australasian Association of Clinical Biochemists (AACB), National Pathology Accreditation Advisory Council (NPAAC) and the Department of Health.

The specific aims of the project included the following:

a. undertake a review of overseas and Australian literature and disseminate the findings to key stakeholders, providing stakeholders with a strong evidence base for assessing relevant models for professional self-regulation;
b. explore the affordability and sustainability of potential models (including support for more efficient quality and risk management in laboratories to support the accreditation assessment processes);
c. conduct intensive case-study-level analysis of overseas examples of certification in scientist professions and Australian attempts at profession self-regulation;
d. undertake a stakeholder analysis which will research current positions of key stakeholders, identifying their expectations, perceived benefits of certification, acceptable parameters for certification in terms of funding, costs, coverage, etc.; and
e. review the *Competency-based Standards for Medical Scientists*[2] and its fitness to underpin a certification system.

This project is a major step towards the long-held goal of MLSs in Australia to have registration of their profession or a similar process.[3] Registration, also called licensure or certification, of medical (laboratory) scientists does occur in

many countries, including the UK, some states in the US, NZ and countries within the EU, amongst others.

In this paper we explore the real and perceived benefits together with the costs of registration and describe the relationship between continuing professional development (CPD) programs and competence. Rather than accepting the notion that registration per se will automatically lead to safer pathology practice, we suggest that the profession should be putting its energies into assessing the competence of scientists to improve their performance and their standing in the community.

What is Registration?

Regulation of health professions enforces minimum standards of expertise and provides a framework for monitoring and accountability. It provides members of the public with an official and clear avenue through which to raise concerns about patient safety and care. Regulation defines clinical standards and outlines a baseline for ethical practice and professionalism. Regulation also prioritises and tracks CPD, which encourages development and maintenance of skills and knowledge.

In the recent review of the Australian Health Practitioner Regulation Agency (AHPRA) scheme[4] the following reasons were given for registration:

a. protecting the public through the registration of health practitioners who are suitably trained and qualified to practise in a competent and ethical manner;
b. facilitating workforce mobility across Australia and reduce red tape for practitioners;
c. facilitating the provision of high quality education and training of health practitioners;
d. facilitating access to services in accordance with the public interest;
e. enabling the continuous development of a flexible, responsive and sustainable health workforce; and
f. enabling innovation in the education of, and service delivery by, health practitioners.

Registration Processes

We present some examples of overseas MLS registration schemes to assist understanding the process involved with a registration-like system. Although maintenance of registration is an essential component, the aspects of the scheme we need to focus on are the entry requirements and the registration authority. These countries have been selected due to their similarities to Australia in more than one of geographical location, culture, population, health care system and/or level of education. Each aspect of an individual system should be assessed, based upon local considerations, as to whether or not they are appropriate for implementation in an Australian certification scheme. Amongst other considerations, a certification scheme could have a significant impact not only on individuals but on educational institutions if it is determined that an accredited degree is required for entry or not.

New Zealand

In NZ, to be registered as a Medical Laboratory Scientist, the person must hold a Bachelor of Medical Laboratory Science (BMLS), which is a four-year degree, obtainable at one of three educational providers in NZ, or an overseas qualification deemed to be substantially similar to a BMLS, or a post graduate degree in a relevant field plus two years of experience in an ISO15189 accredited laboratory. There are paths to registration for other qualifications including 'bridging courses'. The important elements in all of these paths to becoming registered are a suitable academic qualification plus a minimum period of practical medical laboratory-based experience.[5] The NZ registration process is run by the Medical Sciences Council of New Zealand which is an independent body appointed by the Minister of Health.

United Kingdom

In the UK there is a differentiation between Clinical and Biomedical Scientists. For both professions, registration is controlled by the Health Care Professions Council (HCPC) who register Clinical Scientists based on a Certificate of Attainment issued via the Association of Clinical Scientists and Biomedical Scientists based on satisfactory completion of an accredited Institute of Biomedical Science degree.[5-8] In the UK, registration in one discipline is permitted.

Canada

The Canadian Society of Medical Laboratory Science (CSMLS) is a national certifying body and society for Medical Laboratory Technologists (MLTs) and Medical Laboratory Assistants (MLAs) who have a similar scope of practice to Australia's MLSs and Medical Laboratory Technicians respectively. The CSMLS requires examinations to be undertaken by those with approved education streams to gain membership and therefore practice in their respective profession.[9] There is no option to register in only one discipline within the MLT profession.

MLTs in Canada currently require registration with their respective provincial regulatory body, except in some unregulated provinces, e.g. British Columbia. Provincial registration requires the national CSMLS certification, or sometimes equivalent, depending on the jurisdiction. In unregulated jurisdictions, most employers require CSMLS certification as it is often a requirement of the provincial

laboratory accreditors, e.g. Diagnostic Accreditation Program of British Columbia.[10]

Existing associations of the professions in unregulated jurisdictions (British Columbia Society of Laboratory Science) currently encourage professionals to register with them, although it is not mandatory and membership is not popular. The associations, unlike most regulatory bodies, advocate for the profession and provide professional development opportunities. The CSMLS does provide free CPD courses online to members which are also available, at a cost, to non-members.

The Australian National Registration and Accreditation Scheme

In 2010 the Council of Australian Governments established the Australian National Registration and Accreditation Scheme (NRAS), most particularly its administrative arm, the AHPRA.[11] The registered professions at this time are: dental, medical, nursing and midwifery, pharmacy, psychology, Aboriginal and Torres Strait Islander health practice, Chinese medicine, chiropractic, medical radiation practice, occupational therapy, optometry, osteopathy, podiatry and physiotherapy. At the time of formation of the National Scheme, there was an unsuccessful attempt to have MLS included; however, the profession was advised to consider certification.

In 2014 there was a review of the National Scheme which provided information about the costs, benefits and issues in running the registration process.[4] It was recognised that there was a clear difference in the costs and workload of some professions over others. One group, termed the high-regulatory-workload group, which comprised five professions (dental, medical, nursing and midwifery, pharmacy and psychology) accounted for 87.5% of registrants and 95.5% of all complaints and notifications in 2012–13. The Review considered that the regulatory model applied to the remaining nine low-regulatory-workload professions – that account for just 12.5% of registrants and less than 5% of notifications – was neither proportionate nor efficient. It was suggested that to improve the value to these professionals and the Commonwealth, a Health Professions Australia Board be established to replace and manage the regulatory functions of the national boards of the nine low-regulatory-workload professions: Aboriginal and Torres Strait Islander health practice, Chinese medicine, chiropractic, medical radiation practice, occupational therapy, optometry, osteopathy, podiatry and physiotherapy.

The Review also provides a mathematical relationship between the number of registrants and the cost of registration (in 2013–2014) which would suggest the cost for MLSs, based on about 8000 registrants, would be approximately A$200 per MLS.

It was also suggested that a standing committee is needed within the NRAS involving the education sector, national boards, accreditation authorities and representation from employers and jurisdictions to:

a. discuss the means by which health workforce reform and health service access gaps can be best addressed in the education and training of health professionals;
b. consider the evidence and value of alternative innovations in the delivery of health education and training (e.g. simulated learning is accepted by some but not all accreditors);
c. share an understanding of workforce distribution and projected workforce needs; and
d. ensure that education opportunities exist for students to meet the minimum standard of entry.

This recommendation emphasises the important link between registration, education and workforce skilling. The Review also stated that health professionals not included in the National Scheme should not be excluded or disadvantaged professionally; this includes membership of health bodies, access to research grants, or employment simply on the basis that they are not regulated through the National Scheme.

The Review suggested three options to achieve this outcome for consideration by ministers:

a. a clear statement and communique from ministers reinforcing that inclusion in the National Scheme is for the purpose of regulation to ensure public safety, and that exclusion from the National Scheme simply recognises that such professions are adequately regulated through other means, including self-regulation, or do not require additional regulation;
b. clarify the purpose in the national law so it is clear that the National Scheme is for the purpose of additional regulation of specified professions only and is not to be used for any other purpose; and
c. establish a system of quality assurance for voluntary registers so that self-regulated professions can opt for a third-party independent assessment to become accredited. This would be similar to the role of the UK Professional Standards Authority which accredits voluntary registers of people working in a variety of health and social care occupations.

What is a Medical (Laboratory) Scientist?

Registration requires the definition of the profession and the protection of the title so that it could not be used by

another profession or group. While the term Medical Scientist is used in some Australian industrial awards, it is not universal. However, the titles Medical, Biomedical or Clinical Laboratory Scientist are used in the UK, NZ and US, so it would be sensible to use a similar term. MLSs work in clinical laboratories in hospitals, doctors' offices, reference laboratories, biotechnology labs and non-clinical industrial laboratories.[12]

NPAAC in Australia defines a scientist as a person who possesses one of the following qualifications: a degree in science or applied science with subjects relevant to the field of pathology, awarded after not less than three years full-time study, or an equivalent period of part-time study, at a university in Australia, that provides for direct entry or following examination to a professional class of membership of the AACB, AIMS, Australian Society for Microbiology, Australian Society of Cytology or Human Genetics Society of Australasia.[13]

This raises the next question: what is the appropriate entrance qualification for a MLS? There are no statistics available, but it is likely that only about 50% of scientists who work in clinical laboratories in Australia hold an MLS degree from an AIMS-accredited course,[14] while the remainder would have BSc equivalents majoring in biochemistry, microbiology or genetics.

Certification

Registration is not an option for the Australian MLS workforce so the HCA project is examining a certification process instead. Because of the cost and complexity of current registration procedures, certification is seen to be a more cost-effective means for the profession to achieve the goals set out above. What is different about certification and regulation? Certification systems are overwhelmingly voluntary[15-18] though there are examples of professions where certification has become mandatory (US National Occupational Therapy Credentials Board and the American Dietetic Association's Council on Dietetic Registration).[18] This is in contrast to regulation, by which the law mandates that the professional working within the jurisdiction must be registered appropriately.

However, certification is seen as an attractive option for professionals. Indeed, it can become a requirement or the default position, due to the perceived value for the individual, employing organisation or general public.[19-21]

Achieving Certification

Most certification schemes place boundaries or hurdles to accessing or seeking to access certification. Certification entry requirements typically include:

a. sufficient or entry-level educational experiences[16,22-24]
b. completed training with an accredited or approved training program[23,24]
c. a defined or minimum time of practical experience[17]
d. current practising in their profession.[17]

Entry requirements need to be carefully considered and must be defensible, fair and reasonable so as not to exclude qualified candidates.[18] Assessment of competency is generally conducted through a combination of methods of assessment for the attainment of initial certification and recertification. Assessments for initial certification, in addition to minimum entry requirements, can include:

a. examination,[16,23] including online examination
b. logbooks, for example a log of cases of techniques practised and utilised[20,22]
c. oral assessment or interview[15]
d. self-assessment[15]
e. portfolio that demonstrates evidence against performance standards or competencies.[17]

The method of assessment for certification, and particularly recertification, needs to be transparent, well-documented and relevant to the profession, with an appeal process.

On-going Registration and CPD

Once individuals are registered, there is a requirement to maintain that registration through a renewal process. In both NZ and in the UK, this is through demonstration of CPD. The underlying assumption is that such CPD shows a commitment to maintaining skills and knowledge, which in turn ensures that the individual remains competent. Thus, in NZ, a CPD programme for medical scientists is run by the professional body, the New Zealand Institute of Medical Laboratory Scientists. The process involves attending or participating in various educational activities for which points are awarded and each registrant has to accumulate a minimum number of points over three years.[11] In the UK, the HCPC sets standards for CPD which registrants must meet and the HCPC audits a random sample (2.5%) of all registrants at each renewal, which includes a review of CPD claims of the registrant.[12]

In Australia there is no registration to encourage or mandate CPD and, perhaps not surprisingly, there is a poor level of CPD by laboratory scientists. This is evident by relatively low attendance at scientific meetings and activities and, anecdotally, this is also apparent at accreditation visits conducted by the National Accreditation and Testing Agency even though it is a requirement under ISO 15189. Often auditors will state that many staff are not involved in any external education programs, they are not members of

scientific associations and they do not utilise self-educational facilities. It should be noted that CPD also comes at a cost, so the additional cost of meeting these requirements for large employers may be significant or, for individuals, may not seem worthwhile when it is not compulsory.

A question is: does CPD, and therefore registration, necessarily translate to competency and therefore improved patient safety? As the HCPC states in its document *Continuing professional development and your registration*: 'There is no automatic link between your CPD and your competence. This is because it would be possible (although unlikely) for a competent professional not to undertake any CPD yet still meet our requirements for their skills and knowledge. Equally it would be possible for a registrant who was not competent to complete a lot of CPD activities but still not be fit to practise.'[25] Likewise, NZ has a process that considers competency separately from CPD. Perhaps one way to resolve this dilemma is to look at additional ways to assess competency.

Competency

Registration can be considered as a two-part process where individuals initially satisfy certain requirements to become registered and then maintain their registration through ongoing demonstration of competence. Fundamentally, people need to be competent in their job, where competency has been defined as 'the ability to perform the activities within an occupation or function to the standard expected in employment'.[26] Thus, the term 'competency' embodies attributes such as knowledge, skills, abilities and attitudes required in professional practice.

Competency assessment is required under ISO 15189 but there is much variation in determining appropriate competencies and then having an objective process to assess them. In NZ, competency is assessed through a Scope of Practice document which defines the tasks, titles and qualifications associated with medical laboratory science.

In general, any competence assessment scheme needs the following:

- Why – safety, accuracy, efficiency, quality, best practice
- What – a defined process measured against agreed standards
- When and Where – Currency of skills, how often? For how long? At what time? Workplace – 'real life', simulated environments
- Who – supervisor/ manager/ peer review/ customer feedback (internal and external)/ HR
- How – evidence collection, validity, sufficiency, authenticity, make a judgement.

Some certification schemes rely only on achievement of qualifications as a demonstration of suitable competence, and so the onus of certification effectively falls back onto the accreditation of courses, leaving the certification scheme only limited standing. More often, though, certification systems require the development of standards to measure competence.[18] Generally, these standards also become the benchmark for assessing suitable qualifications (i.e. the accreditation process). Competency standards can include a combination of technical and professional skills,[15] as well as non-technical skills that might include critical cognitive skills and interpersonal abilities such as skills in communication and collaboration that complement technical skills.[27]

Defining the standards to measure someone as 'competent' can be achieved through the development of a competency framework. A competency framework provides a model of the desired outcome by defining required competencies as well as how they should be assessed;[22] therefore structured and validated competency-based curricula and assessments are seen as a necessary tool for a certification program.[27]

Development of competency frameworks is in some cases undertaken by the certifying body,[28] or by regulatory agencies, training institutes or working groups from the profession.[22,29] The Pathology Associations Council (PAC) in Australia, which comprises membership of all the professional bodies involved in pathology practice, has developed a competency-based standard for MLSs which provides definitions of appropriate competencies. The PAC also determined the appropriate level of competency required for different classes of staff in what is called the Scope of Practice document.[2,30] This is comprised of the following units:

Unit 1: Collection, preparation and analysis of clinical material

Unit 2: Correlation and validation of results of investigations using knowledge of method(s) including analytical principles and clinical information

Unit 3: Interpretation, reporting and issuing of laboratory results

Unit 4: Maintenance of documentation, equipment, resources and stock

Unit 5: Maintenance and promotion of safe working practices

Unit 6: Professional accountability and participation in continuing professional development

Unit 7: Responsibility for Medical Science practice including test selection, development and use of laboratory investigations

Unit 8: Liaison with health workers and others to continuously improve the service

Unit 9: Participation in education and training of health workers and others
Unit 10: Contribution to advancement of knowledge and improvement of laboratory practice

While these documents describe the various competencies required for MLSs and other grades of laboratory staff, they do not deal with the process to determine if a particular MLS reaches those competencies. Such a process has not yet been agreed upon but it needs to be robust, objective, reproducible and transferrable.

These competencies have been endorsed by all members of the PAC and could be used as the basis of competency assessment programs, both internal and external, by which the competence of a scientist (indeed any staff member) could be determined. Competency assessment could be a two-tiered process, analogous to quality control and quality assurance. After training has been completed and a staff member is deemed acceptable for the job, there would need to be periodic competency assessment as required by ISO 15189 Clause 5.1.11.[31] One critical competency assessment level (QC) would be the internal level, where various tasks and demonstrated learning would be devised using the competency-based standards described above.

At a global level, and to reassure the public, what is required is an external assessment analogous to external quality assurance or proficiency testing which would involve an independent agency that would regularly assess competence in all critical scientific staff. The forms of assessment would depend on the type of work undertaken, but all would involve tasks where competence is critical.[32]

Alternatives to CPD for the Medical Profession

The issues raised in this paper about the need to ensure ongoing competency are not unique to medical laboratory scientists. Even registered professions are beginning to raise doubts about enrolment in CPD programs as being sufficient evidence of continuing competency. Internationally in medicine and medical regulation, there is discussion about revalidation for medical practitioners and how it can support patient safety. The International Association of Medical Regulatory Authorities, defines revalidation as '...the process by which doctors have to regularly show that they are up to date, and fit to practice medicine. This will mean that they are able to keep their license to practice, sometimes referred to as "recertification".'[33]

Certification and Accreditation

There is a close relationship between certification of professionals and accreditation of courses producing those professionals. It is obvious that accredited programs of study and education providers are graduating students who have the knowledge, clinical skills and professional attributes necessary to practise the profession. It is also important that there is independence of the accreditation decisions from the stakeholders being regulated and that there is an involvement of consumers. One clear benefit of registration is that it provides reasonably reliable workforce data. A register of all medical scientists in Australia would be a valuable asset and provide guidance as to how many graduates we need from the tertiary sector for a sustainable workforce. An ongoing relationship between the accrediting group and the education providers would facilitate this certification/accreditation aim.

Currently AIMS accredits MLS courses but there are many other pathways by which an MLS can enter the workforce. The certification body should be able to inform if workforce numbers are insufficient or excessive, and if the skill levels are deficient. Because of the lag time between these changes and changes to numbers of graduating students, this is not an efficient process.

A standing committee is needed within the National Scheme involving the education sector, national boards, accreditation authorities and representation from employers and jurisdictions to:

a. discuss the means by which health workforce reform and health service access gaps can be best addressed in the education and training of health professionals;
b. consider the evidence and value of alternative innovations in the delivery of health education and training (an example is that simulated learning is accepted by some but not all accreditors);
c. share an understanding of workforce distribution and projected workforce need; and
d. ensure that education opportunities exist for students to meet the minimum standards of entry.

Conclusions

The Australian MLS workforce is considering the adoption of a self-managed certification scheme. The profession has demanded a registration scheme for decades but had been unsuccessful in achieving this goal, yet many of the aims of such a scheme would be available in a certification model. There are various association-run CPD schemes which give credit points for various activities including attendance at scientific meetings, self-development, reading relevant journal articles, being a member of a professional committee or other workplace roles. However, they are generally not well-supported and do not provide the up-skilling necessary to bring new competencies to the profession. CPD schemes do not address many of the core requirements of a competency

assessment program in that they are voluntary, sometimes non-audited, they are not core skills-oriented, and are non-standardised. A universal competency-based certification scheme will lead to greater recognition of the MLS workforce and greater protection for the public. It is our view that our profession should support this opportunity wholeheartedly for the benefit of our profession.

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